K041784

SEP 13 2004

510(k) Summary

510(k) Notification
ProTest – EO Biological Indicator

Submitted by:	Raven Biological Laboratories 8607 Park Drive Omaha, NE 68127
Contact:	Wendy Royalty-Hann Quality Assurance/Regulatory Affairs Manager Or Robert V. Dwyer, Jr. President Phone: (402) 593-0781 Fax: (402) 593-0921
Prepared on:	
Device:	Trade name: ProTest – EO Biological Indicator Common name: Self-contained Biological Indicator for Ethylene Oxide Sterilization
Classification:	Class II
Predicate Device:	SGM EZTest® - GAS (K930683)

DESCRIPTION

The biological indicator consists of a self-contained unit that includes bacterial spores of *Bacillus atrophaeus* ATCC #9372 inoculated onto a paper filter carrier and a small glass ampoule containing modified Tryptic Soy Broth with Bromothymol Blue acting as a pH indicator encased in a plastic vial that serves as the culture tube.

OPERATIONAL PRINCIPALS

The ProTest – EO Biological Indicator is placed with a load in the sterilization chamber and subjected to a normal ethylene oxide sterilization cycle. The unit is then removed and activated by crushing the glass media ampoule inside. The processed unit and an unprocessed (control) unit are incubated at 30-35°C for 48 hours.

During incubation, the available food supply (Tryptic Soy Broth) and temperature promote growth of any viable spores. As viable spores germinate and consume the provided nutrients waste products are released, increasing the acidity of the media which lowers the pH and causes a color change from green to yellow.

Evidence of growth by color change and/or turbidity within 48 hours should be interpreted as a failure to meet the conditions necessary for sterilization, provided signs of growth are present in the control unit.

STATEMENT OF SIMILARITY TO LEGALLY MARKETED PREDICATE DEVICE

ProTest – EO is similar in composition and function to the legally marketed predicate device EZTest – Gas.

- Both are intended for use in monitoring ethylene oxide sterilization cycles.
- Utilize the same strain of bacterial spores.
- Utilize the same carrier material.
- Virtually the same size and shape.
- Activated in the same manner.

DESCRIPTION OF TESTING

Testing was performed in accordance with AAMI ST59:1999 to validate the labeled claims and performance characteristics of ProTest – EO.

Three separate lots of product manufactured from three different primary spore crops were tested for resistance, spore population, recovery of low numbers of injured spores, and a reduced incubation period of 48 hours. For all lots tested, the above parameters and overall effectiveness in monitoring routine ethylene oxide sterilization cycles has been demonstrated.

STATEMENT OF SAFETY AND EFFECTIVENESS

Based on the similar claims, design and results from the above mentioned testing, the ProTest – EO Biological Indicator has been demonstrated to be substantially equivalent to and therefore, as safe and effect as, the legally marketed device EZTest – Gas.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2004

Ms. Wendy Royalty-Hann
Quality Assurance/Regulatory Affairs Manager
Raven Biological Laboratories, Incorporated
8607 Park Drive
Omaha, Nebraska 68127

Re: K041784
Trade/Device Name: Raven ProTest-EO
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: June 28, 2004
Received: July 1, 2004

Dear Ms. Royalty-Hann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

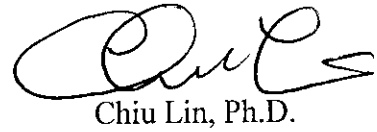
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K041784

Device Name Raven ProTest – EO

Indications for Use Raven ProTest – EO is a self-contained Biological Indicator inoculated with viable *Bacillus atrophaeus* bacterial spores and is intended for monitoring the efficacy of ethylene oxide sterilization cycles. Raven ProTest – EO has a validated reduced incubation time of 48 hours.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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